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EXAMINER

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ART UNIT 1807 | PAPER NUMBER 19

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Please address communications from the examiner in charge of your application to:
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-126 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-126 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1800, Art Unit 1807.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The probes directed to the CML otaining lack enablement due to a lack of availability of the probes that flank the fused BCR and ABL sequences. Note the non-publicly available probes (pCV105 and PEM12) supplied as disclosed in the specification on page 115, lines 11-16.

On page 55, genomic libraries are listed as being specific for each of the human chromosomes. It is noted that these are

described as being available from the ATCC but there is no indication as to their being available so as to meet all of the criteria as listed and required below. Additionally there is no enablement of the procurement of targeted "fetal" versus other chromosomal material as cited in claim 4. This material is different from mature chromosomal material due to the differentiation that is known to occur in maturation of an individual.

It is noted that the chromosome-specific libraries listed on page 55 have been deposited with the ATCC. Since these libraries as well as the probes pCV105 and PEM12 are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the libraries and probes are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the libraries and probes. The specification does not disclose a repeatable process to obtain the libraries and probes and it is not apparent if the libraries and clones are readily available to the public. It is noted that applicants have listed the ATCC deposit numbers for the libraries but there is no clear indication in the specification as to public availability. If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the libraries and probes have been deposited under the Budapest Treaty and that the

libraries and probes will be irrevocably and without restriction or condition released to the public upon issuance of a patent, would satisfy the deposit requirement made herein.

If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in MPEP 608.01(p)C, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposits will be replaced if they should ever become inviable.

Claims 1-126 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 10-19, 21, 30, 31, 36-41, 44, 45, 50-53, 55, 56, 103, 108, 110, 115, 118, and 125 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims

limited to the use of probes that have been specifically disclosed as being associated with the claimed disease as either CML, ALL, etc. Undue experimentation would be required to define probes where the association to the disease is previously unknown. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 8-21, 27-31, 35-41, 43-45, 49-56, 98-101, 103, 105-119, and 125 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 cites a "translation breakpoint" without a clear concise definition of its location. The term "regions" in line 3 of claim 12 is vague and indefinite. What are the metes and bounds of the practice of the phrase "vicinity of the translocation breakpoint regions" cited in claim 12? What are the metes and bounds of the genetic rearrangements cited in claim 10 that are "diagnostic" of CML? What rearrangements are "associated" with ALL as given in the last line of claim 21? In summary, the above rejected claims recite methods and probes for disease associated rearrangements but do not clearly and concisely define what probe composition is required so as to relate staining to the disease. In the case of specific probes as discussed within the specification for CML diagnosis, the probe practice is defined for a certain probe set but not for probes beyond those specifically disclosed. There is no clear and concise guidance as to alter already known probes for each

disease so as to define the wide variety of possibly usable probes as implied by the broad claim language. What are the metes and bounds of the probe practice of the above rejected claims?

In claim 12, line 2, the term "homologous" is cited without a clear definition of the homology being claimed.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 51-53, 56, and 125 are rejected under 35 U.S.C. § 101 because there is no showing that the probes instantly disclosed have usefulness in therapeutic regimens, monitoring the status of a patient, or searching for residual disease in a patient. It is well known that such usefulness must be well documented by data showing such utility in order to satisfy the utility requirement.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7, 22-26, 32, 34, 42, 46, 47, 57-60, 66, 71-75, and 120-122 are rejected under 35 U.S.C. § 102(b) as being anticipated by Langer-Safer et al.

Langer-Safer et al. disclose probes to targeted chromosomal material. The common finding of rearrangements in chromosomes makes all chromosomes suspect as to the presence of rearrangements and the unclarity as to what is meant by the term "vicinity" as discussed above permits the anticipation of the instant claims by Langer-Safer et al. Human metaphase chromosomal material is disclosed by Langer-Safer et al. on page 4385, first column, first sentence of the last paragraph.

Claims 1-3, 6-9, 22, 23, 26-28, 32-35, 42, 43, 46, 47, 49, 54, 57, 60-64, 66, 71-74, 93, 98, 101, 102, 105-107, 109, 116, 117, and 120-124 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Montgomery et al.

Montgomery et al. discloses the specific staining of chromosomes in Figure 3 on page 5727 including the preparation, characterization, and use of the probes in the "Materials and Methods" section bridging pages 5724 and 5725. This disclosure reads on the instant claims due to the broad wording of the instant claims.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-126 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-126 of copending application Serial No. 07/497,098. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of serial no. 07/497,098 have been amended to more clearly disclose the claimed subject matter but have not been amended so as to alter the essentials of the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or

patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 2, 1991

Ardin Marschel

ARDIN MARSCHEL
PATENT EXAMINER
ART UNIT 1807